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EXAMINER	
KRAMER, NICOLE R	

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 04/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/723,316	SPINELLI ET AL.	
	Examiner	Art Unit	
	Nicole R. Kramer	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 November 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

1. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1-27 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-27, 36-37 of copending Application No. 10/236,578. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present application is merely broader than the ' 578 application (that is, the present application allows for lead implantation at more locations than the '077 application and allows for such stimulation to treat more conditions). The more specific claims of the '578 application anticipate the broader claims of the present application, and thus the two claims are not patentably distinct. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

4. Claim 1-6 and 10-23 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 16-17 and 29-31 of copending Application No. 10/422,077. Although the conflicting claims are not identical, they are not patentably distinct from each other because both set of claims require an implanted electric pulse generator, an electrode electrically coupled to the pulse generator, wherein the electrode is implanted at the colon of the patient in order to treat constipation. The present application is merely broader than the ' 077 application (that is, the present application allows for lead implantation at more locations than the '077 application and allows for such stimulation to treat more conditions). The more specific claims of the '077 application anticipate the broader claims of the present

application, and thus the two claims are not patentably distinct. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

5. Claims 7-8 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 7, 32, and 38 of copending Application No. 10/723,903. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present application is merely broader than the ' 903 application (that is, the present application allows for lead implantation at more locations than the '903 application). The more specific claims of the '903 application anticipate the broader claims of the present application, and thus the two claims are not patentably distinct. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

6. Claims 7-8 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 7, 32, and 38 of copending Application No. 10/745,757. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present application is merely broader than the ' 757 application (that is, the present application allows for lead

implantation at more locations than the '757 application). The more specific claims of the '757 application anticipate the broader claims of the present application, and thus the two claims are not patentably distinct. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

7. Claim 27 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/836,355. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present application is merely broader than the ' 355 application (that is, the present application allows for lead implantation at more locations than the '355 application). The more specific claim of the '757 application anticipate the broader claim of the present application, and thus the two claims are not patentably distinct. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

8. Claim 27 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/836,840. Although the conflicting claims are not identical, they are not patentably

distinct from each other because the present application is merely broader than the ' 840 application (that is, the present application allows for lead implantation at more locations than the '840 application). The more specific claim of the '840 application anticipate the broader claim of the present application, and thus the two claims are not patentably distinct. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

9. Claims 7-8 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 7 of copending Application No. 10/836,924. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present application is merely broader than the ' 924 application (that is, the present application allows for lead implantation at more locations than the '924 application). The more specific claims of the '924 application anticipate the broader claims of the present application, and thus the two claims are not patentably distinct. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

10. Claims 7-8 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 7 of copending Application No. 10/836,927. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present application is merely broader than the ' 927 application (that is, the present application allows for lead implantation at more locations than the '927 application). The more specific claims of the '927 application anticipate the broader claims of the present application, and thus the two claims are not patentably distinct. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

11. Claim 27 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/836,970. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present application is merely broader than the ' 970 application (that is, the present application allows for lead implantation at more locations than the '970 application). The more specific claim of the '970 application anticipate the broader claim of the present application, and thus the two claims are not patentably distinct. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

12. Claim 27 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/837,181. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present application is merely broader than the ' 181 application. The more specific claim of the '181 application anticipate the broader claim of the present application, and thus the two claims are not patentably distinct. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

14. Claims 1-2, 9, 14-19, 24, and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by "Neural Stimulation as a method of controlling prostatitis symptoms" (Chalfin), disclosed in 1999 Selected Abstracts from the American Urological Association annual meeting.

Chalfin discloses the use of sacral nerve stimulation for treatment of chronic prostatitis. The abstract provided from the 1999 the American Urological Association annual meeting discloses the method of claim 1, in that an implanted pulse generator and a medical lead are provided and implanted into the patient. The medical lead (Examiner considers "medical lead" to encompass the wire electrode disclosed in Chalfin) contains an electrode and necessarily contains proximal and distal ends. The medical lead is implanted adjacent to sensory nerves that supply the bladder, rectum, and pelvic floor. Although not explicitly disclosed, the proximal end of the lead is necessarily connected to the implantable pulse generator to enable the electrical signals to be applied to the targeted nerve. Electrical stimulation pulses are applied to the targeted nerve to provide the patient with at least partial relief from pain resulting from prostatitis.

With respect to claim 2, Examiner considers "unipolar lead" to encompass the wire electrode disclosed in Chalfin.

With respect to claim 14, the lead of Chalfin necessarily has a length. Examiner considers "less than about 4 inches, about 4 inches, about 6 inches, about 8 inches, about 10 inches, about 12 inches, about 14 inches, about 16 inches about 18 inches,

about 20 inches and more than about 20 inches" to encompass any possible length of a medical lead, and thus the lead of Chalfin anticipates claim 14.

With respect to claims 15 and 17, the implanted generator disclosed in Chalfin necessarily comprises an electronic circuitry architecture selected from the group consisting of a microprocessor-based architecture, a logic architecture and a state machine architecture in order to generate electrical pulses. Further, the implanted pulse generator necessarily contains a power source in order to generate electrical pulses.

With respect to claims 16 and 18, Chalfin discloses that the patient can control the implanted pulse generator with an external programming unit (a hand held transmitter).

With respect to claim 19, the medical lead is configured for percutaneous introduction and implantation within the patient (the wire electrode is implanted through incisions).

With respect to claim 24, Chalfin discloses that the electrical stimulation pulse regime provided to the patient is effective in providing urinary frequency relief.

With respect to claim 26, Chalfin discloses the use of drug therapies.

15. Claims 1, 2, 7-8, and 14-27 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,454,840 ("Krakovsky et al.").

Krakovsky et al. discloses an implanted device called a potency package that includes a battery 40, a programmable signal circuit 42, and a pulse generator 46 (see col. 3, lines 25-35). The device includes a medical lead having an electrode, which

connects with the pelvic splanchnic nerves (see col. 3, lines 49-55) (Examiner considers "medical lead" to encompass the electrode running from the implantable pulse generator to the target nerve as shown in Figures 5 and 11). The potency package delivers electrical stimulation pulses (see col. 3, lines 35-45) in order to provide the patient with at least partial relief from erectile/sexual dysfunction.

With respect to claim 2, Examiner considers "unipolar lead" to encompass the electrode disclosed in Krakovsky et al.

With respect to claims 7-8, Krakovsky et al. discloses a second electrode (49) extending from the device to the pudendal nerves (see col. 4, lines 5-19).

With respect to claim 14, the lead of Krakovsky et al. necessarily has a length. Examiner considers "less than about 4 inches, about 4 inches, about 6 inches, about 8 inches, about 10 inches, about 12 inches, about 14 inches, about 16 inches about 18 inches, about 20 inches and more than about 20 inches" to encompass any possible length of a medical lead, and thus the lead of Krakovsky et al. anticipates claim 14.

With respect to claim 15, the implanted generator disclosed in Krakovsky et al. necessarily comprises an electronic circuitry architecture selected from the group consisting of a microprocessor-based architecture, a logic architecture and a state machine architecture in order to generate electrical pulses.

With respect to claim 17, the potency package contains a power source (battery 40).

With respect to claims 16 and 18, Krakovsky et al. discloses that the unit is controlled with an external control unit (see col. 3, lines 31-37).

With respect to claim 19, the medical lead is configured for percutaneous introduction and implantation within the patient (see col. 5, lines 5-27).

With respect to claims 20-23, see Figs. 12 and 13 that illustrate preferred pulse programs of the potency package device.

With respect to claim 24, Krakovsky et al. discloses the teachings of the invention may be used for urine incontinence correction during sexual intercourse (see col. 6, lines 40-46).

With respect to claims 26-27, Krakovsky et al. discloses that the potency package may contain a chamber (60), electronic pump (62), and thin tube (64) for storing and delivering a drug to the penis (see col. 4, lines 28-53).

16. Claims 1-4, 7-9, 14-15, and 17-20 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,002,964 ("Feler et al.").

Feler et al. discloses a method of managing chronic pelvic pain through application of electrical energy to selected sacral nerve roots. The stimulation system includes an implanted signal generator (see col. 6, lines 19-25) that generates an electrical signal having an amplitude, pulse width, and frequency adjusted to finely select the nerve tissue required to inhibit transmission of pain signals (see col. 6, lines 26-37). The electrodes for electrical stimulation of the selected sacral nerves may be carried by percutaneous leads (see col. 3, line 50 - col. 4, line 65) or by laminotomy leads, which carry multiple electrodes on a planar surface (i.e., a paddle configuration) (see col. 5, line 55 - col. 6, line 19).

With respect to claim 2, Feler et al. discloses that each electrode of each lead may be defined as a positive, negative, or a neutral polarity (see col. 6, lines 25-30).

With respect to claims 3-4, Feler et al. discloses that the electrodes for electrical stimulation of the selected sacral nerves may be carried by laminotomy leads, which carry multiple electrodes on a planar surface (i.e., a paddle configuration) (see col. 5, line 55 - col. 6, line 19).

With respect to claims 7-8, Feler et al. discloses two implantable leads implanted at the sacral nerve (see Figs. 3 and 4 and associated text).

With respect to claim 9, electrical stimulation is provided to induce paresthesia (see col. 3, lines 35-50).

With respect to claim 14, the lead of Feler et al. necessarily has a length. Examiner considers "less than about 4 inches, about 4 inches, about 6 inches, about 8 inches, about 10 inches, about 12 inches, about 14 inches, about 16 inches about 18 inches, about 20 inches and more than about 20 inches" to encompass any possible length of a medical lead, and thus the lead of Feler et al. anticipates claim 14.

With respect to claims 15 and 17, the implanted generator disclosed in Feler et al. necessarily comprises an electronic circuitry architecture selected from the group consisting of a microprocessor-based architecture, a logic architecture and a state machine architecture in order to generate electrical pulses. Further, the implanted pulse generator necessarily contains a power source in order to generate electrical pulses.

With respect to claim 18, Feler et al. discloses that the stimulation system includes an implanted signal generator (see col. 6, lines 19-25) which generates an

electrical signal having an amplitude, pulse width, and frequency adjusted to finely select the nerve tissue required to inhibit transmission of pain signals (see col. 6, lines 26-37).

With respect to claim 19, Feler et al. discloses that the electrodes for electrical stimulation of the selected sacral nerves may be carried by percutaneous leads (see col. 3, line 50 - col. 4, line 65).

With respect to claim 20, Feler et al. discloses that the signal frequencies for inhibiting transmission of signals along sensory nerves may be between 10-25,000 Hz (see col. 6, lines 37-44).

17. Claims 1-5 and 10-23 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,238,423 ("Bardy").

Bardy discloses a system for treating constipation, the system including an implanted stimulus generator (10) located with a fluid-tight housing (9). The implanted stimulus generator is connected to stimulating electrodes (14) via a medical lead (12) (see col. 3, lines 35-55). The stimulating electrodes stimulate a target portion (17), which may be any part of the patient's descending colon (16), ascending colon (29), or transverse colon (33) (see col. 6, lines 25-35).

With respect to claims 2-3, see Fig. 3 and associated text.

With respect to claims 4-5, Bardy discloses that anchoring holes (19) assist in stapling or suturing the electrode portion to the target portion (see col. 4, lines 1-4).

Alternatively, a fibrous cuff (25) may be provided along the lead 12 to assist in stapling or suturing the electrode portion to the target portion (see col. 4, lines 5-7).

With respect to claim 10, Examiner considers connecting portion 15 of the lead to be a lead extension extending between electrode portion 11 of the lead and the pulse generator.

With respect to claim 11, Bardy discloses that any part of the implanted system may be made from polyurethane or silicone (see col. 3, lines 40-45).

With respect to claim 12, Bardy discloses that the inter-electrode distance may be about 2 mm (see col. 5, lines 20-27).

With respect to claim 13, Bardy discloses that the electrodes may have a surface area of 3 sq. mm (see col. 5, lines 45-55).

With respect to claim 14, the lead of Bardy necessarily has a length. Examiner considers "less than about 4 inches, about 4 inches, about 6 inches, about 8 inches, about 10 inches, about 12 inches, about 14 inches, about 16 inches about 18 inches, about 20 inches and more than about 20 inches" to encompass any possible length of a medical lead, and thus the lead of Bardy et al. anticipates claim 14.

With respect to claims 15-17, Bardy discloses that the stimulus generator includes a pulse generator (47), a power supply (48), a microprocessor controller (54), and telemetry means (58) (see col. 9, lines 5-10). Telemetry means (58) are utilized for communicating with an external receiver (see col. 9, lines 50-65).

With respect to claims 18 and 20-23, see Figs. 6 and 7 and associated text.

With respect to claim 19, the leads are configured for percutaneous implantation within a patient (see col. 6, lines 33-36).

18. Claims 1-2, 11, 14-15, 17-24 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,449,512 ("Boveja").

Boveja teaches an implantable system for treating urinary incontinence disorders, the system including a hermetically sealed implanted pulse generator 70 (see col. 6, line 52) for providing the appropriate pulses to the sacral plexus of a patient via two electrodes 61,62 in contact with the sacral nerves (see col. 6, lines 37-48). Conductors insulated by silicone or polyurethane are used for connecting the electrodes to the pulse generator (see col. 6, lines 42-46). The circuitry of the pulse generator contains a microprocessor 72 driven by lithium batteries 76 (see col. 6, lines 45-48). The microprocessor controls the program parameters of the device, such as the voltage, pulse width, frequency, and duration of the stimulation (see col. 7, lines 25-30).

With respect to claim 2, Boveja discloses that the lead may be bipolar (see col. 8, lines 40-65).

With respect to claim 14, the lead of Boveja necessarily has a length. Examiner considers "less than about 4 inches, about 4 inches, about 6 inches, about 8 inches, about 10 inches, about 12 inches, about 14 inches, about 16 inches about 18 inches, about 20 inches and more than about 20 inches" to encompass any possible length of a medical lead, and thus the lead of Boveja et al. anticipates claim 14.

With respect to claims 20-23, see col. 7, lines 33-67.

Claim Rejections - 35 USC § 103

19. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

20. Claims 4-8 and 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over "Neural Stimulation as a method of controlling prostatitis symptoms" (Chalfin), or U.S. Patent No. 6,002,964 ("Feler et al."), or U.S. Patent No. 6,449,512 ("Boveja"), in view of U.S. Patent No. 6,055,456 ("Gerber").

As discussed above, Chalfin and Feler et al. and Boveja teach implanted stimulation systems for stimulating portions of the sacral nerves for treatment of various ailments, such as prostatitis, chronic pelvic pain, or urinary incontinence disorders. Gerber teaches a prior art implantable medical lead for stimulation of the sacral nerves that simplifies the implant procedure (i.e., see col. 2, lines 30-40). It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the stimulation system of Chalfin/Feler et al./Boveja to utilize the medical lead as taught by Gerber in order to simplify the implant procedure while still providing adequate electrical stimulation to the sacral nerve.

With respect to claims 4 and 5, Gerber teaches the lead has an active fixation device (see anchoring mechanism 50 and associated text).

With respect to claim 6, Gerber teaches that one or more electrodes of the lead can be configured to operate in conjunction with an electrically conductive portion of the pulse generator (i.e., see col. 4, line 65 - col. 5, line 5).

With respect to claims 7-8, Gerber teaches that implanting two medical leads for delivering electrical stimuli is known in the art (see col. 1, lines 35-55). It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the stimulation system of Chalfin to utilize the multiple leads in a stimulation system as taught by Gerber in order to stimulate multiple target areas simultaneously or sequentially.

With respect to claim 10, Gerber does not explicitly disclose that a lead extension may be utilized. Examiner takes Official Notice that lead extensions are well known in the art. It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the stimulation system of Chalfin/Feler et al./Boveja to utilize a lead extension in order to modify the length of a lead to a desired length for implantation.

With respect to claim 11, Gerber teaches a lead body having a diameter of .050 inches (or 1.27 mm), the lead body being made of polyurethane or silicone (col. 4, lines 5-12).

With respect to claim 12, Gerber teaches an inter-electrode distance of the first lead of about 16 mm (see col. 4, lines 30-55; when the first electrode contact 20 is 0.40 inches and the second electrode contact 40 starts 1 inch from the distal tip, the inter electrode distance is about 16 mm).

With respect to claim 13, the electrode surface area ranges between 1.0 square mm and 100 square mm (i.e., the embodiment of Fig. 1 discloses an electrode having .1 inch to 1.5 inches length and a diameter of preferably 0.5 inches. In an embodiment where the length of electrode 20 is 1 inch, the surface area of the electrode is approximately 40 mm).

Conclusion

21. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

U.S. Patent Application Publication 2005/0209652 ("Whitehurst et al.") teaches an implantable system for treating erectile dysfunction via electrical stimulation and/or drug infusion. The electrodes and/or infusion outlets may be implanted adjacent any structure of the penis, including the pelvic splanchnic nerves, certain sacral nerves, the prostatic plexus, the hypogastric nerves, the pudendal nerves, and the urethra (see paragraph 0100).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicole R. Kramer whose telephone number is 571-272-8792. The examiner can normally be reached on Monday through Friday, 8 a.m. to 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

NRK
3/24/06

George Manuel
Primary Examiner